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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,948	02/17/2004	Mark D. Erion	MET-016XDT	2285

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EXAMINER
LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,948	ERION ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-132 and 138-167* is/are pending in the application.

4a) Of the above claim(s) *98-102,104-119,122,123,125,126 and 138-141* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-97,103,120,121,124,127-132,142-146,148,149,152-155,157-159 and 161-167* is/are rejected.

7)☒ Claim(s) *147,150,151,156 and 160* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07272006; 08312006; 10182006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Compound H and troglitazone (species election) in the reply filed on June 18, 2007 is acknowledged.

2. Claims 98-102, 104-119, 122, 123, 125, 126 and 133-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 18, 2007.

3. Claims 95-132 and 138-167 are pending. Claims 98-102, 104-119, 122, 123, 125, 126 and 138-141 are drawn to a nonelected species. An action on the merits of claims 95-97, 103, 120, 121, 124, 127-132 and 142-167 is contained herein.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 142, 146, 152-155 and 164-167 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a mammal having diabetes, does not reasonably provide enablement for preventing a mammal from acquiring diabetes. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

1. the breadth of the claims;
2. the nature of the invention;
3. the state of the prior art;
4. the level of one of ordinary skill in the art;
5. the level of predictability in the art;
6. the amount of direction provided by the inventor;
7. the existence of working examples; and
8. the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims are drawn a method for treating or preventing diabetes comprising administering an insulin sensitizer agent and an FBPase inhibitor. The USPTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as the would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. This means that the words of the claim must be given their plain meaning unless

applicant has provided a clear definition in the specification. Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. The ordinary and customary meaning of the term "prevent" is "to keep from happening : AVERT" (WEBSTER'S II).

"An Update on Type 2 Diabetes in Youth From the National Diabetes Education Program", Pediatrics (2004), Vol. 114, pages 259-263 (Pediatrics) is representative of the state of the art at the time of the invention in regards to the treatment and prevention of diabetes. Diabetes and related conditions are very complex with no known means of prevention via pharmacological methods. Pediatrics teaches, "Diabetes prevention in children requires modifying a complex set of behavior patterns. Peer pressure and the social environment are especially influential in children." No examples are provided in the instant specification showing the prevention diabetes. The instant disclosure also fails to provide rationale which lead one of ordinary skill in the art to predict that diabetes is prevented using the instant composition. Due to the lack of guidance provided in the specification and the level of unpredictability in the art, one of ordinary skill in the art would not be able to practice the instant invention without undue experimentation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 103, 120-121, 124, 148-149, 153-155, 157-158, 161-162 and 165-166 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The variable "M" has not been defined in the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 95-97, 103, 120-121, 124, 127-132, 142-146, 148-149, 153-155, 157-159, 161-163 and 165-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahoo et al. US 6,008,237 (Sahoo) in combination with Dang et al. US 6,284,748 (Dang).

Claims 95-97, 103, 120-121, 124, 127-132, 142-146, 148-149, 153-155, 157-159, 161-163 and 165-167 are drawn to a method of treating or preventing diabetes in a mammal comprising administering to said mammal an insulin sensitizer agent and an FBPase inhibitor.

Sahoo teaches a method for the treatment, control, or prevention of diabetes, hyperglycemia, hyperlipidemia, atherosclerosis, obesity, vascular restenosis, and other PPAR-mediated diseases, disorders and conditions employing compounds of Formula I (column 16). Examples of other active ingredients that may be combined with a compound of Formula I, either administered separately or in the same pharmaceutical compositions, include insulin sensitizers such as troglitazone.

Sahoo differs from the instantly claimed method in that Sahoo does not teach the co-administration of troglitazone and an FBPase inhibitor; however, this deficiency

would have been obvious to one of ordinary skill in the art in view of the teachings of Dang.

Dang teaches purine compounds of Formula 1 that are inhibitors of FBPase at the AMP site (column 1, lines 10-17). The compounds are useful for treating diabetes and other diseases where inhibition of gluconeogenesis, control of blood glucose levels, reduction of glycogen stores, or reduction in insulin levels is beneficial. The compounds may be administered by a variety of means including orally, parenterally, by inhalation spray, topically, or rectally (column 38, lines 32-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat diabetes in a mammal by co-administering an insulin sensitizer agent such as troglitazone and an FBPase inhibitor such as the furan phosphoric acid compounds taught by Dang. Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious as the idea of combining them flows logically from their having been individually taught in the prior art. In the instant case, Sahoo teaches a method for the treatment, control, or prevention of diabetes, hyperglycemia, hyperlipidemia, atherosclerosis, obesity, vascular restenosis, and other PPAR-mediated diseases, disorders and conditions using compositions comprising insulin sensitizer agents; Dang teaches the use of FBPase inhibitor for treating diabetes and other diseases where inhibition of gluconeogenesis, control of blood glucose levels, reduction of glycogen stores, or reduction in insulin levels is beneficial. Thus claims that require no more than the administration of two conventional anti-diabetic compositions together in order to treat diabetes prima facie obvious.

Conclusion

12. Claims 95-132 and 138-167 are pending. Claims 98-102, 104-119, 122, 123, 125, 126 and 138-141 are drawn to a nonelected species. Claims 95-97, 103, 120-121, 124, 127-132, 142-146, 148-149, 152-155, 157-159, and 161-167 are rejected. Claims 147, 150-151, 156 and 160 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dr. Patrick T. Lewis
Primary Examiner
Art Unit 1623

ptl